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EXAMINER

CELSA, BENNETT M

ART UNIT

PAPER NUMBER

1639

DATE MAILED: 07/25/2003

5

Please find below and/or attached an Office communication concerning this application or proceeding.

file copy

Office Action Summary

Application N .

09/767,538

Applicant(s)

WANG ET AL.

Examiner

Bennett Celsa

Art Unit

1639

-- The MAILING DATE of this communication appears in the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-50 is/are pending in the application.
- 4a) Of the above claim(s) 1-36, 40-42 and 50 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 37-39 and 43-49 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Status of the Claims

Claims 1-50 are currently pending.

Claims 37-39 and 43-49 are under consideration.

Claims 1-36, 40-42 and 50 are withdrawn from consideration as being directed to a nonelected invention.

Election/Restrictions

Applicant's election with traverse of Group III (claims 37-49) in Paper No. 5 is acknowledged. . Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Applicant's further election of

- a. DNA (as specific type of reagent);
- b. Supports (claims 43-45; as barrier species); and
- c. Applying conditions (claims 48-49; as species of contacting) is also

acknowledged .

The traversal is on the ground(s) that

Regarding the agent species election, applicant argues that the method is the same for each reagent species and species reactivity is not correlated to patentable distinctness . This is not persuasive since the reagent species possess different structures and modes of action which elicit different issues regarding patentability e.g. a method practices using a peptide may be nonobvious over a reference which teaches

Art Unit: 1639

the same or similar method which is directed to a nucleotide; and additionally, the selection of a nucleotide vs. a peptide elicits a different and separately burdensome bibliographic/classification search; especially in the present instance where there is a list of structurally/functionally distinct classes of compounds in the claimed Markush.

Turning to the barrier species election, applicant argues that the use of capillary tubes vs. the use of supports in the presently claimed method "do not require disparate structure or mode to create significantly different issues of patentability". This argument was considered but not deemed persuasive since, the selection of a barrier species (e.g. capillary tube v. support) elicits different issues regarding patentability since the selection of particular barrier species may distinguish over the prior art; and applicant is not admitting that one species would necessarily render the other species obvious. Additionally, the selection of a particular barrier species would elicit different and separately burdensome bibliographic searches.

Upon further consideration the requirement for election of a "contacting species" is hereby withdrawn.

The requirement (as modified above) is still deemed proper and is therefore made FINAL.

Claim Objections

Claim 37 (line 1) is objected to because of the following informalities: "twp" should be --- two-- . Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

Art Unit: 1639

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 46 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 46 the phrase "said step of **providing two** or more biological targets" lacks antecedent basis.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 37-39, 43-45 and 47-48 are rejected under 35 U.S.C. 102(b) as being anticipated by Shalon et al. WO 95/35505 (12/95). Shalon et al. teaches both a method and apparatus for making micro arrays comprising "two or more reagents" (e.g. 2 or more polynucleotides or polypeptides) and "one or more barriers ... wherein each portion is maintained at predefined positions ... portions is adapted to be brought into contact with one or more predefined biological targets" in which the "barrier"

Art Unit: 1639

comprises a "solid support" (e.g. uncoated or glass coated with a polymer i.e. polylysine and grids e.g. addresses) . See e.g. abstract; pages 7-8; claims and figures (especially fig. 3). The Shalon et al. polymer arrays are then subjected to assay which comprises the correspondence to and contacting of "biological target(s)" (e.g. polynucleotides/polypeptides) to the predefined reagent portions (e.g. see figures, especially fig. 5-12). It is noted that the reference teaches "seeding and adhering biological targets" of claim 47 where the targets *are non-cellular* (e.g. DNA/protein) since contacting of the reference reagent to its target effectuate "seeding and adhering" within the scope of the presently claimed invention. Similarly, the reference teaching of applying (in any manner) the reagent to its target meets "the step of applying one or more conditions" (where conditions are open-ended: e.g. include physical/chemical/mechanical and other parameters) since such conditions would include not only the application but the temperature and/or physical parameters exercised by the reference procedure.

Claims 37-39, 43-44 and 47-48 are rejected under 35 U.S.C. 102(e) as being anticipated by Chin et al. US Pat. No. 6,197,599 (3/01: filed 7/98). Chin et al. teach both a method and apparatus for making (micro)arrays comprising "two or more reagents" (e.g. 2 or more "agents" including proteins and "small molecules": see col. 3) and "one or more barriers ... wherein each portion is maintained at predefined positions ... portions is adapted to be brought into contact with one or more predefined biological targets" in which the "barrier" comprises a "solid support" (e.g. glass/plastic plates or membranes including PVDF, nylon etc. : see e.g. col. 4). The Chin et al. polymer

Art Unit: 1639

arrays are then subjected to assay (e.g. see examples, especially examples 3 and 4) which comprises the correspondence to and contacting of "biological target(s)" (e.g. polypeptides) to the predefined reagent portions (e.g. see figures 1-4; and patent claims) It is noted that the reference teaches "seeding and adhering biological targets" of claim 47 where the targets *are non-cellular* (e.g. protein) since contacting of the reference reagent to its target effectuate "seeding and adhering" within the scope of the presently claimed invention. Similarly, the reference teaching of applying (in any manner) the reagent to its target meets "the step of applying one or more conditions" (where conditions are open-ended: e.g. include physical/chemical/mechanical and other parameters) since such conditions would include the application but the temperature and/or physical parameters exercised by the reference procedure.

Claims 37-39 and 43-49 are rejected under 35 U.S.C. 102(e) as being anticipated by Sabatini US Pat. No. 6,544,790 (4/03: filed 9/99). Sabatini teaches both a method and apparatus for making (micro)arrays comprising "two or more reagents" (e.g. DNA/RNA: bottom of col. 1 to top of col. 2) and "one or more barriers ... wherein each portion is maintained at predefined positions ... portions is adapted to be brought into contact with one or more predefined biological targets" in which the "barrier" comprises a "solid support" (e.g. any "flat surface" including slides made of glass which can be polymer coated e.g. with polylysine; or bottom of wells in multi-welled plates: see col. 2). The Sabatini reference further teaches "providing one or more biological targets" which include cells grown on "growth supports" and/or applied (seeded/adhered) to the DNA/RNA reagent while employing growth medium (DMEM)

Art Unit: 1639

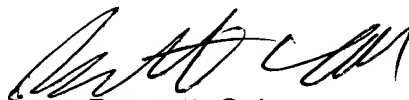
(e.g. see col. 4). The Sabatini reference method further teaches the use of any transfection technique (e.g. see col. 1, especially lines 30-40) including electroporation (e.g. electric pulse) as a condition to facilitate transfer (e.g. transfection) of the DNA/RNA into the target cell (s). See also figures and patent claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bennett Celsa whose telephone number is 703-305-7556. The examiner can normally be reached on 8-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 703-306-3217. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Bennett Celsa
Primary Examiner
Art Unit 1639

BC
July 24, 2003